

ANTISEPTIC HAND WASH- alcohol and diazolidinylurea liquid
Medical Chemical Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Medi Fect Label

Ingredients: 70% v/v ethyl alcohol, propylene glycol, emollients (polysorbate 80, cetyl alcohol, acetylated lanolin alcohol), carbomer, diazolidinyl urea, methyl paraben, aloe vera and propyl paraben. Contains emollients and skin conditioners. Contains no added fragrance or dyes.

Directions: Place a 'palmful' (about 5 g) of product in one hand. Spread on both hands and rub into the skin until dry (approximately 1 to 2 minutes). Place a smaller amount (2.5 grams) into one hand, spread over both hands to wrist, and rub into skin until dry (approximately 30 seconds).

Indications for use: For hospital and professional use only. Medi-Fect is intended to be used as a hand-wash to reduce bacteria that can potentially cause disease. Recommended for repeated use.

Warnings: Flammable, keep away from fire or flame. For external use only. Do not use in the eyes. Discontinue use if irritation or redness develops. Keep out of reach of children. In case of ingestion contact poison control center immediately.

MediFect Label



Medi-Fect™
Antiseptic
Hand-Wash
(with Aloe Vera)



Manufactured by Medical Chemical Corp.
Torrance, CA 90501

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NDC# 012745-177E

ANTISEPTIC HAND WASH

ethyl alcohol liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:12745-177

| | | | |
|--------------------------------|---------|---------------------|--|
| Route of Administration | TOPICAL | DEA Schedule | |
|--------------------------------|---------|---------------------|--|

| Active Ingredient/Active Moiety | | |
|--|--------------------------|-------------------|
| Ingredient Name | Basis of Strength | Strength |
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 59.86 g in 100 mL |
| DIAZOLIDINYLUREA (UNII: H5RIZ3MPW4) (DIAZOLIDINYLUREA - UNII:H5RIZ3MPW4) | DIAZOLIDINYLUREA | 1.00 g in 100 mL |

| Inactive Ingredients | |
|-------------------------------------|-------------------|
| Ingredient Name | Strength |
| DIISOPROPYLAMINE (UNII: BR9JLI40NO) | 0.505 g in 100 mL |
| WATER (UNII: 059QF0KO0R) | |

| Packaging | | | | |
|------------------|------------------|-------------------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:12745-177-01 | 118 mL in 1 BOTTLE, PLASTIC | | |
| 2 | NDC:12745-177-02 | 473 mL in 1 BOTTLE, PLASTIC | | |
| 3 | NDC:12745-177-03 | 3785 mL in 1 BOTTLE, PLASTIC | | |
| 4 | NDC:12745-177-04 | 18927 mL in 1 BOTTLE, PLASTIC | | |

| Marketing Information | | | |
|------------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph final | part333 | 05/14/2001 | |

Labeler - Medical Chemical Corporation (008496861)

| Establishment | | | |
|------------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Medical Chemical Corporation | | 008496861 | manufacture |